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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,736

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Justin R. Fallon

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ROPES & GRAY LLP

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EXAMINER

CHERNYSHEV, OLGA N

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/081,736	<b>Applicant(s)</b> FALLON ET AL.	
	<b>Examiner</b> Olga N. Chernyshev	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13, 16, 32 and 34-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 16, 32 and 34-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 13, 36, 37 and 39 have been amended and claims 45-46 have been added as requested in the amendment filed on July 02, 2008. Following the amendment, claims 13, 16, 32 and 34-46 are pending in the instant application.

Claims 13, 16, 32 and 34-46 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on July 02, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13, 16, 32 and 34-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 13 stands rejected as being vague and indefinite for recitation "an abnormal dystrophin-associated protein complex (DAPC)", see reasons of record in section 9 of Paper mailed on January 04, 2008. Applicant traverses the rejection by providing examples of abnormalities of DAPC, see pp. 5-6 of the Response. The Examiner maintains that because the term "abnormal DAPC" is not an art-recognized term and because the instant specification does

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not identify that property or combination of properties which is unique to and, therefore, definitive of an “abnormal DAPC”, an artisan cannot determine if a cell having a DAPC complex which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

7. Claim 39 stands indefinite as being incomplete for omitting essential steps, such omission amounting to a gap between the steps for reasons of record in section 10 of Paper mailed on January 04, 2008. Applicant argues at pp. 6-7 of the Response that Example 10 teaches exemplary activity of MuSK. However, Examples 10 describes only one activity that appears to pertain to the instant invention, such as agrin-induced phosphorylation of MuSK. Therefore, it is not obvious what other activities are intended by the claim and what are the steps to assay that activities. Applicant is advised that incorporation of claim 46 into claim 39 would obviate this ground of rejection.

8. Claim 13, **as currently amended**, is vague and indefinite for recitation “the cell-surface receptor muscle, skeletal receptor tyrosine kinase (MuSK)”. The metes and bounds of the recitation cannot be determined from the claim or the instant specification as filed.

9. **Newly added claim 45** is vague and ambiguous for recitation “abnormal DAPC is caused by [...] an abnormally low level of, a DAPC component”. The metes and bounds of the recitation cannot be determined from the claim or the instant specification, Furthermore, “an abnormally low level” is a relative term, for which no point of reference to define the limitation is present in the claim.

10. Claims 16, 32, 34-38, 40-44 and 46 are indefinite for being dependent from indefinite claims.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 13, 16, 32 and 34-44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al., US Patent No. 5,654,270 for reasons of record in previous communications of record.

Applicant traverses the rejection essentially on the premises that “[s]ince Ruoslahti does not teach administration of a biglycan therapeutic to a cell with abnormal DAPC, Applicants believe that withdrawal of the 102(b) rejection is appropriate”, p. 8 of the Response. Applicant’s arguments have been fully considered but are not persuasive. The Examiner has already addressed this rejection in the previous communications of record. The Examiner maintains the same position. Briefly, since the instant specification fails to specifically point out what represents an abnormal DAPC, the disrupted muscular tissue of the wound, by broadest reasonable interpretation fully encompasses cells with abnormal DAPC, absence evidence to the contrary. Therefore, by practicing contacting wounded muscular cells with the product of identical structure, biglycan of SEQ ID NO: 9, as taught by the document of Ruoslahti et al., activation of cell-surface structures is achieved and, thus, the instant invention is anticipated.

Applicant is advised that because biglycan therapeutic has been shown to have a biphasic effect on cell activation (Example 10, p. 83), including the concentration range, which enables practicing the instant method, would distinguish the instant claims and the prior art of record.

***Double Patenting***

13. Claim 44 stands rejected on the ground of nonstatutory double patenting over claims 1-14 of U. S. Patent No. 6,864,236 for reasons of record in section 14 of Paper mailed on January 04, 2008.

***Conclusion***

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 30, 2008

/Olga N. Chernyshev, Ph.D./  
Primary Examiner, Art Unit 1649